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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,255	07/31/2003	Michael J. Heller	612,404-424	3292

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EXAMINER	
SISSON, BRADLEY L	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 08/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/632,255	HELLER, MICHAEL J.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision in *University of Rochester v. G.D. Searle & Co.* 68 USPQ2D 1424 (Fed. Cir. 2004) at 1428:

> To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. Vas-Cath, 935 F.3d at 1563; see also Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"); In re Gosteli, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) ("the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written-description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572.

3. For convenience, claim 1 is reproduced below.

1. (Original) A method for forming a multiple identity substrate material comprising the steps of:

providing a first affinity sequence at multiple locations on a support;

providing a functionalized second affinity sequence, which reacts with the first affinity sequence, and has an unhybridized overhang sequence; and

selectively cross-linking first affinity sequences and second affinity sequences.

4. Page 7, bridging to page 8 of the disclosure provides a summary of the invention, and a description of its application.

This invention relates to methodologies and manufacturing techniques which utilize programmable functionalized self-assembling nucleic acids, nucleic acid modified structures, and other selective affinity or binding moieties as building blocks for: (1) creating molecular electronic and photonic mechanisms', (2) for the organization, assembly, and interconnection of nanostructures, submicron and micron sized components onto silicon or other materials; (3) for the organization, assembly, and interconnection of nanostructures, submicron and micron sized components within perimeters of microelectronic or optoelectronic components and devices', (4) for creating, arraying, and manufacturing photonic and electronic structures, devices, and systems; (5) for the development of a high bit density (large byte) three and four dimensional optical data storage materials and devices; and (6) for development of low density optical memory for applications in authentication, anti-counterfeiting, and encryption of information in documents or goods. This invention also relates to associated microelectronic and optoelectronic devices, systems, and manufacturing platforms which provide electric field transport and selective addressing of self- assembling, nanostructures, sub-micron and micron size components to selected locations on the device itself or onto other substrate materials.

5. A review of the disclosure fails to find an adequate written description of a method whereby useful sequences would be identified, and used in the method such that data storage and retrieval can be achieved, be the resultant product used in an electronic or photonic mechanism. Further, the specification has not been found to set forth such full, clear, and concise language that which would permit one of skill in the art to recognize the resultant multiple identity substrate that is useful in data storage and retrieval from that which is not useful.

Attention is directed to the decision of *Vas-Cath Inc. v. Mahurkar* 19 USPQ2d 1111 (CAFC, 1991):

> This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 USC 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the "applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed.*

6. The specification has shown that four oligonucleotide sequences have been used in a method whereby a "nanostructure" was created. The specification, however, does not go on to show that any one, much less all, of these nanostructures were used or useful in "(1) creating molecular electronic and photonic mechanisms', (2) for the organization, assembly, and interconnection of nanostructures, submicron and micron sized components onto silicon or other materials; (3) for the organization, assembly, and interconnection of nanostructures, submicron and micron sized components within perimeters of microelectronic or optoelectronic components and devices', (4) for creating, arraying, and manufacturing photonic and electronic structures, devices, and systems; (5) for the development of a high bit density (large byte) three and four dimensional optical data storage materials and devices; [or] (6) for development of low density optical memory for applications in authentication, anti-counterfeiting, and encryption of information in documents or goods."

7. For the above reason, and in the absence of convincing evidence to the contrary, claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Response to argument

8. At page 5 of the response received 05 June 2006 argument is presented in that the nucleotide sequence is not important "but rather the resulting substrates having multiple identities, as exemplified by multi-colored areas of the substrate."

9. The above argument has not been found persuasive as the very color, or selection of colors, and their associated hues, are all dependent upon the composition of the DNA, i.e., the adenine, thymine, cytosine, and guanine residues. In short, it is the very nucleotide sequence that is to, at least in part, impart the color of the substrate. The specification does not provide an adequate written description of just which sequences result in any given color. Further, the specification does not provide an adequate written description of how these very sequences are to then be utilized in a method of data storage and retrieval.

While assertions are made at page 7 that "multiple identity substrates resulting from the claimed method can subsequently be used for optical data storage devices, which are useful in authentication, anti-counterfeiting and encryption application." A review of applicant's remarks and of the disclosure as filed fails to locate where the disclosure adequately describes just how such tasks are to be performed. Attention is directed to the decision of *Vas-Cath Inc. v. Mahurkar* 19 USPQ2d 1111 (CAFC, 1991):

> This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 USC 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the "applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed.*

In view of the foregoing remarks, and in the absence of convincing evidence to the contrary, the rejection of claims 1-12 under 35 USC 112, first paragraph, under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is maintained.

10. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth in *Enzo Biochem Inc., v. Calgene, Inc.* (CAFC, 1999) 52 USPQ2d at 1135, bridging to 1136:

> To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).... We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, *e.g.*, *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In *In re Wands*, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

11. A review of the disclosure finds an example where a nanostructure was made. However, the specification is silent as to how one is to use the nanostructure in any of the recited and intended utilities. It is not enough that the specification teaches how to make a novel product. The specification must enable the use of that which is produced. In the instant case, the specification is essentially silent as to how one is to use the resultant product in any disclosed method that withstands a test of utility. Therefore, and in the absence of convincing evidence to the contrary, claims are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

Response to argument

12. At page 7 of the response received 05 June 2006, traversal is made of the rejection of claims under 35 USC 112, second paragraph, as it relates to issues of enablement. It is noted with particularity that no claim was rejected under 35 USC 112, second paragraph. Further, it is noted that said second paragraph of 35 USC 112 does not address issues of enablement. Rather, said second paragraph addresses issues of clarity.

13. At page 7 of said response argument is presented that the specification teaches that the substrate could be caused to emit photons at predetermined and multiple wavelengths, with attention being directed to page 41 and Fig. 45. A review of the specification finds that the last paragraph on page 41 provides forward looking statements as to "using DNA polymers for high density optical data storage media." The specification does not set forth a reproducible procedure by which such a method could be reproducibly practiced. Clearly, the specification does not set forth the reaction conditions or requisite starting materials. The situation at hand is

analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the decision of the Court:

> " '[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.' *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) ('[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.').
>
> *****
>
> "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.') Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.
>
> "It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research. (Emphasis added)

Accordingly, and in the absence of convincing evidence to the contrary, claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

14. Claims 1-12 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible and substantial asserted utility or a well established utility.

15. The specification lists 6 intended utilities for the resultant product: (1) creating molecular electronic and photonic mechanisms', (2) for the organization, assembly, and interconnection of nanostructures, submicron and micron sized components onto silicon or other materials; (3) for the organization, assembly, and interconnection of nanostructures, submicron and micron sized components within perimeters of microelectronic or optoelectronic components and devices', (4) for creating, arraying, and manufacturing photonic and electronic structures, devices, and systems; (5) for the development of a high bit density (large byte) three and four dimensional optical data storage materials and devices; and (6) for development of low density optical memory for applications in authentication, anti-counterfeiting, and encryption of information in documents or goods." Of the six recited utilities, 1-4 are not viewed as being substantial. For example, manufacturing "molecular electronic and photonic mechanisms" for the sake of making them, when they have no specific and substantial utility is not deemed to meet the utility requirements of 35 USC 101. Similarly, the organization of nanostructures for their interconnection does not in and of its self rise to the level of a substantial utility.

16. Utilities identified as elements (5) and (6) are deemed to be substantial, however, they are not found to be credible. As set forth above, the specification has not been found to provide an adequate written description of resultant "multiple identity substrate material" that has been disclosed as useful in a reproducible method, where such method is any of the disclosed utilities.

17. For the above reasons, and in the absence of convincing evidence to the contrary, claims 1-12 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible or substantial asserted utility or a well established utility.

18. Claims 1-12 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Response to argument

19. At page 8 of the response of June 5, 2006, argument is presented in that the Office has not presented sufficient basis to question the utility of the invention.

20. The above argument has not been found persuasive as the prior Office action and the instant action both specifically address the aspect of multiple asserted utilities not constituting a "substantial utility." Such statements, in contrast to applicant's remarks, do not question whether it can or cannot work, but that they acts described do not rise to the level of a substantial utility.

While additional argument has been presented that the invention may be useful "in high density and low density optical storage, including, for example, incorporation into documents, currency, labels and as replacements for bar codes that may be "read" according to standard laser techniques," a review of the disclosure and of the prior art fails to find where such utilities existed in readily available form at the time of filing. Further, applicant's remarks also fail to provide evidence of their existence at the time of filing. It matters not whether the claim is drawn to a product or process; the claim must be drawn to an invention that satisfies the utility requirements as set forth under 35 USC 101 and as further developed in the Utility Guidelines.

In support of this position, attention is directed to *Brenner, Comr. Pats. v. Manso*n, 148 USPQ 689 (US Sup Ct 1966):

> Whatever weight is attached to the value of encouraging disclosure and of inhibiting secrecy, we believe a more compelling consideration is that a process patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute. Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development, 22 without compensating benefit to the public. The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.
>
> * * *
>
> We find absolutely no warrant for the proposition that although Congress intended that no patent be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use-testing, a different set of rules was meant to apply to the process which yielded the unpatentable product. 24 That proposition seems to us little more than an attempt to evade the impact of the rules which concededly govern patentability of the product itself.
> This is not to say that we mean to disparage the importance of contributions to the fund of scientific information short of the invention of something "useful," or that we are blind to the prospect that what now seems without "use" may tomorrow command the grateful attention of the public. But a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. (Emphasis added)

21. For the above reasons, and in the absence of convincing evidence to the contrary, the rejection is maintained.

Terminal Disclaimer

22. The terminal disclaimer filed on 05 June 2006 disclaiming the terminal portion of any patent granted on this application that would extend beyond the expiration date of US Patent 6,652,808 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Conclusion

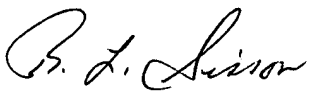
23. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

24. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

27. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS